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Browdy and Neimark
419 Seventh Street NW
Suite 300
Washington DC 20004-2299

In Re: Patent Term Extension Application for U.S. Patent No. 5,156,957

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OFFICE OF PETITIONS

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,156,957, which claims the human drug product GONAL-F, follitropin alpha/beta, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,605 days. U.S. Patent No. 5,156,957 has an original expiration date of May 8, 2007, as determined by the terminal disclaimer and subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,605 days will result in an extended expiration date of September 29, 2011.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,605 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 30, 1999 (64 Fed. Reg. 23338). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (569-237) + 1,605
= 1,641 days

Since the regulatory review period began February 26, 1992, before the patent issued (October 20, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 26, 1992 to September 29, 2011 is 237 days;[1] this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.[2]

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (September 29, 1997) when added to the period of extension calculated above (1,641 days) cannot exceed fourteen years. The period of extension calculated above, 1,641 days, would extend the patent from May 8, 2007 to November 4, 2011, which is beyond the 14-year limit (the approval date is September 29, 1997, thus the 14 year limit is September 29, 2011). The period of extension is thus limited to September 29, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, May 8, 2007 to and including September 29, 2011, or 1,605 days.

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[1]This is the period set forth in 37 CFR 1.775(d)(1)(i).

[2]This would have been the period set forth in 37 CFR 1.775(d)(1)(ii).

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,156,957
Granted	:	October 20, 1992
Original Expiration Date	:	May 8, 2007
Applicant	:	Vemuri B. Reddy, et al.
Owner of Record	:	Genzyme Corporation
Title	:	Follicle Stimulating Hormone
Classification	:	435/69.4
Product Trade Name	:	GONAL-F, follitropin alpha/beta
Term Extended	:	1,605 days
Expiration Date of Extension	:	September 29, 2011

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: GONAL-F, follitropin alpha/beta
FDA Docket No.: 98E-0488